

**REMARKS/ARGUMENTS**

Applicants submit the aforementioned amendments in response to the Final Office Action mailed February 7, 2007. A Request For Continued Examination (RCE) is concurrently submitted herewith.

Claims 1-4 and 7-10 are canceled.

Claims 5 and 6 have been amended.

Claims 5 and 6 are subject to the examination. Reconsideration is respectfully requested in view of the above amendment and the following remarks.

**Rejection under 35 USC 112, paragraph 2**

The Examiner rejects claim 5 and 6 under 35 USC 112, paragraph 2 as being indefinite for the reason that the claim term “mutation 386A” does not identify “what strain of HIV and what protein region the number 386 is in reference to, neither is it clear what amino acid is being mutated to A.”

The term “mutation 386A” has been amended to “T386A”, which is a common expression for a specific amino acid mutation. The amended term now clearly indicates that it is a mutation from amino acid threonine (T) to alanine (A) at position 386 of HIV reverse transcriptase.

In addition, Applicants herewith submit part IV of a document entitled “The 2000 HIV sequence compendium” published well before the priority date (1 July 2002) of the instant patent application. This document is available via the link [www.hiv.lanl.gov/content/](http://www.hiv.lanl.gov/content/) as mentioned in the description of our patent application on page 2, line 13.

When visiting this web page, more specifically [www.hiv.lanl.gov/content/index](http://www.hiv.lanl.gov/content/index) and by clicking on “sequence database” accordingly, the complete “2000 HIV sequence compendium” can be downloaded for free. This document was, as mentioned on its front page, last modified on February 8, 2002, so also well before the priority date of our patent application. A person skilled in the art is, without any burden, able to go to said part IV, more specifically starting on page 457 running through page 530 (herewith enclosed <http://www.hiv.lanl.gov/content/hiv-db/COMPENDIUM/2000/HIV1proteins.pdf> ) and finds out that the reverse transcriptase wild

type or reference sequence starts at the first line on page 482 with the amino acid sequence well known as “PISPIET” (annotated on page 482 at the top as: “p66, p51 RT”). Following the reverse transcriptase amino acid sequence as provided, the wild type 386 position in reverse transcriptase can easily be found on page 488 of the enclosed document and is indicated as a “T” amino acid in said wild type HIV amino acid sequence. The mutation according to the invention is the 386A mutation in HIV reverse transcriptase accordingly; the description of a genetic mutation as such, in this field of technology, is given in our patent application on page 2, lines 15-20. In the description on page 2, line 27 a reference is made to wild type virus (HIV IIIB / LAI) used as reference sequence and deposited in GenBank under accession number K03455, GeneID 327742, which is a unique accession number used at the priority of the present patent application (July 1<sup>st</sup>, 2002) and which is currently still in use in GenBank under the same accession number containing the same sequence information as the sequence information mentioned in the enclosed “The 2000 HIV sequence compendium” also published well before our priority date (1 July 2002).

Applicants herewith submit that for the skilled person these references are clear and disclose unambiguously for the present application a way to determine the specific amino acid at position 386 in HIV reverse transcriptase. The skilled artisan can unambiguously reduce the claimed subject matter to practice using the teaching disclosed in the current application without any undue experimentation.

Accordingly, the rejection to claims 5 and 6 under 35 USC 112, paragraph 2, has been overcome and should be withdrawn.

#### **Rejection under 35 USC 112, first paragraph**

The Examiner rejects claims 5 and 6 under 35 USC 112, first paragraph, stating that “the claimed method only determines the presence of one mutation in HIV reverse transcriptase (RT), which would only confer resistance to HIV RT inhibitors but not fusion inhibitors, protease inhibitors, and integrase inhibitors.”

Applicants have amended claims 5 and 6 to direct the invention to HIV RT inhibitor. Accordingly, the rejection to claims 5 and 6 under 35 USC 112, first paragraph, has been overcome and should be withdrawn.

**Rejection under 35 USC 102(a)**

The Examiner rejects claims 5 and 6 under 35 USC 102(a), as being anticipated by Margot et al.

Margot et al. teaches an evaluation of virological response and mutational profiles in ARV-experienced patients by adding tenofovir to their existing regimens. Nowhere in Margot et al. discloses HIV reverse transcriptase mutation T386A.

The present invention is specifically directed to a method of evaluating drug susceptibility of HIV mutation T386A to a reverse transcriptase inhibitor. Since Margot et al. does not teach mutation T386A, it does not teach each and every element of the claims, thereby failing to anticipate the present invention.

Accordingly, the rejection to claims 5 and 6 under 35 USC 102(a) has been overcome and should be withdrawn.

Allowance of claims 5 and 6 is respectfully requested.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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